UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF MICHIGAN

DANIELLE GARDNER,

Plaintiff

v.

Case No:
Honorable

ZIMMER, INC., and
ZIMMER HOLDINGS, INC., and

(Related Cases in MDL 2272)

Defendants

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PLAINTIFF'S COMPLAINT

NOW COMES Plaintiff Danielle Gardner, by and through her undersigned attorneys, and for her Complaint against the Defendants, alleges as follows:

PARTIES

1. Plaintiff, Danielle Gardner, is a citizen of the State of Michigan, and resides in the City of Benzonia, County of Benzie.

2. Defendant Zimmer, Inc., is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business in the State of Indiana.

3. Defendant Zimmer Holdings, Inc., is a foreign corporation incorporated under the laws of the State of Delaware and has its principal place of business in Indiana;

JURISDICTION AND VENUE

4. This Court has diversity jurisdiction over the parties pursuant to 28 U.S.C.§1332(a). No Defendant is a citizen of the same state as Plaintiff and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

5. Venue in this judicial district is proper pursuant to 28 U.S.C. §1391(a).

BACKGROUND FACTS

6. The Defendants designed, manufactured, distributed, and sold implantable orthopedic devices for use in knee arthroplasty surgeries, under the name of "Zimmer NexGen Flex Knee" system and procedures, promoting them on the basis of "enhanced" capabilities, "minimally invasive" procedures, and gender specific designs, promising consumers, doctors and patients alike, more movement, shorter hospital stays, and better fit than the existing, well-functioning models.

7. On April 9, 2009, Dr. J. McGraw, M.D. performed a right total knee arthroplasty on the person of Plaintiff Danielle Gardner, including surgically implanting a NexGen Complete Knee Solution CR-Flex *Gender Solutions* Female (GSF CR-Flex) into her right knee. The surgery occurred in Traverse City Michigan.

8. That during the surgery performed on April 9, 2009, Danielle Gardner had the following Zimmer products implanted into her person:

a. NexGen Complete Knee Solution All Poly Patella. Lot Number 61203701. Reference No. 5972-65-32.

b. NexGen Complete Knee Solution Stemmed Tibial Component. Lot Number 61137752. Reference No. 5980-27-02.

c. NexGen Complete Knee Solution Articular Surface Cruciate Retaining. Lot Number 61112732. Reference No. 90-5970-20-10.

d. NexGen Complete Knee Solution CR-Flex GSF Femoral Component. Lot Number 61131059. Reference No. 00-5750-015-02.

9. That in 2006, Zimmer launched Gender Solutions, a femoral component designed specifically for women. Differences between traditional and Gender Solutions Female (GSF) implants include a thinner profile, contoured shape, and a difference in the angle between the pelvis and the knee to more mimic the general anatomic differences between the female and male knee (other than size).

10. That Defendants had knowledge and information confirming the defective and dangerous nature of the Zimmer CR-Flex (GSF).

11. That despite that knowledge and information, Defendants failed to adequately and sufficiently warn Plaintiff and her physician that Zimmer CR-Flex (GSF) causes serious permanent injuries including high failure rate, loosening of the implant, bone loss, decreased range of motion, diminished mobility, and the need for revision surgery.

12. After the implant of the GSF CR-Flex, Plaintiff experienced pain, discomfort, diminished mobility, and exhibited symptoms of a loose implant.

13. Eventually Plaintiff's underwent a revision surgery to remove and replace the CR-Flex GSF due to the inappropriate loosening of the implant and bone loss on June 15, 2010.

14. That following the revision surgery, Ms. Gardner's complaints of pain, discomfort, and mobility restrictions persisted. She underwent a knee fusion on November 15, 2011.

15. As a direct and proximate result of defects in the CR-Flex GSF, the Plaintiff has suffered and will continue to suffer damages, including, but not limited to, past, present and future pain and suffering; disability; disfigurement; expenses for medical, hospital, rehabilitative, and pharmaceutical costs; and lost wages or earnings.

16. Defendants designed, researched, manufactured, tested, sought approval by the U.S. Food and Drug Administration ("FDA") and advertised, promoted, marketed, sold and/or distributed the CR-Flex (GSF) as an appropriate instrumentation for use in a Right Total Knee Athroplasty.

17. Upon information and belief, Zimmer CR-Flex (GSF) is defective in design because of its propensity to loosen and cause patients unnecessary pain and repeat surgical procedures requiring revision resulting in additional bone loss.

18. Upon information and belief, Zimmer CR-Flex (GSF) has an increased risk for failure requiring revision surgery that is unreasonably greater than other knee implant products. The Zimmer CR-Flex (GSF) offers no clinical benefit over the traditional products.

19. At all times relevant hereto, Defendants failed to properly train, instruct and/or inform the FDA and prescribing physicians of the proper technique for installation of the CR-Flex (GSF).

20. At all times relevant hereto, Defendants negligently designed, manufactured, marketed, advertised, promoted, sold and/or distributed the CR-Flex (GSF) as a safe and effective implant for use in Total Knee Arthroplasty.

21. At all times relevant hereto, Defendants failed to warn of the dangers of the GSF CR-Flex, including, but not limited, the fact that the CR-Flex (GSF) can unexpectedly loosen

from the knee joint.

22. Upon information and belief, Defendants concealed their knowledge of the defects in GSF CR-Flex from the Plaintiff, the physicians, the hospitals, and/or the FDA.

23. Consequently, because of Defendants' acts and omissions, Plaintiff seeks damages including, but not limited to:

a) pain and suffering (past and future);

b) wage loss (past and future);

c) earning impairment;

d) medical expense (past and future);

e) loss of enjoyment of life;

f) mental anguish and distress;

g) permanent injuries and impairment; and

h) attorney fees.

COUNT I -FAILURE TO WARN

24. Plaintiff hereby restates and alleges each and every allegation set forth above with the same force and effect as if herein repeated and set forth at length.

25. Defendants developed, manufactured, marketed, and distributed the CR-Flex (GSF) implanted in Plaintiff Danielle Gardner and sold it in the course of their business, even after acquiring knowledge that the CR-Flex (GSF) was defective and dangerous and could cause injury, without any warning to physicians or patients, including Plaintiff Danielle Gardner and her physicians.

26. As a direct and proximate result of Defendants' failure to warn of this serious

risk, the Plaintiff Danielle Garnder has suffered substantial damages.

27. The CR-Flex (GSF) was expected to, and did, reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition with which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

28. At all times, the CR-Flex (GSF) was in an unsafe, defective, and inherently dangerous condition which was unreasonably dangerous to its users and, in particular, Plaintiff Danielle Gardner.

29. The CR-Flex (GSF) was so defective in design or formulation or manufacture that when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design, formulation, or manufacture of the CR-Flex (GSF).

30. At all relevant time, the CR-Flex (GSF) was in a defective condition and unsafe, and Defendants knew, had reason to know, or should have known that said product was defective and unsafe, especially when used in the form and manner as provided by Defendants.

31. Defendants had a duty to create and sell a product that was not unreasonably dangerous for its normal, intended use.

32. Defendants' CR-Flex (GSF) product was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed in a defective or inadequate condition by Defendants and was unreasonably dangerous and created an unreasonable risk to its intended users, including Plaintiff Danielle Gardner.

33. Plaintiff Danielle Gardner, acting as a prudent person, could not discover that the CR-Flex (GSF) was defective as herein mentioned or perceive its danger.

34. The CR-Flex (GSF) as designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by the Defendants is defective due to inadequate warnings, inadequate instructions, and/or inadequate testing.

35. The CR-Flex (GSF) as designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by the Defendants is defective due to inadequate post-marketing surveillance and/or warnings because, upon information and belief, sales continued after Defendants knew, or should have known, of the manufacturing defects and risks, including severe and permanent health consequences.

36. Defendants' defective design, manufacturing defect, inadequate instructions and inadequate warnings of the dangers associated with the CR-Flex (GSF) were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

37. As a direct and proximate result of the defective condition of the CR-Flex (GSF) due to inadequate warnings, inadequate instructions, and/or inadequate testing, Plaintiff Danielle Gardner suffered and continues to suffer damages.

COUNT II – PRODUCT LIABILITY

38. Plaintiff hereby restates and alleges each and every allegation set forth above with the same force and effect as if herein repeated and set forth at length.

39. Defendants' defective product proximately caused damage to the Plaintiff which said damage was caused by a characteristic of the product that rendered it unreasonably dangerous arising from a reasonably anticipated use of the product by the Plaintiff, thus rendering Defendants liable to the Plaintiff.

40. The product in question is unreasonably dangerous for reasons including the

following:

a) It is unreasonably dangerous in construction or composition;

b) It is unreasonably dangerous in design;

c) It is unreasonably dangerous because an adequate warning about the product was not provided; and

d) It is unreasonably dangerous because it does not conform to an express warranty of the manufacturer about the product.

41. The characteristics of the product that render it unreasonably dangerous existed at the time the product left the control of the manufacturer or resulted from a reasonably anticipated alteration or modification of the product.

42. For all the reasons alleged herein, Defendants defective product was unreasonably dangerous in construction and composition because, at the time the product left its manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance for the product, or from otherwise identical products manufactured by the same manufacturer.

43. For all the reasons alleged herein, Defendants' defective product was unreasonably dangerous in design at the time the product left its manufacturer's control in that:

a) There existed an alternative design for the product that was capable of preventing the Plaintiff's damages; and

b) The likelihood that the product's design would cause the Plaintiff's damages and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative

design on the utility of the product.

44. For all the reasons alleged herein, Defendants' defective product was unreasonably dangerous because an inadequate warning about the product, including inadequate warning on instruction for installment of the product, had not been provided and at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage and the Defendants failed to use reasonable care to provide adequate warning of such characteristic and its danger to users and handlers of the product.

45. Further, the Defendants, after the product left their control, acquired knowledge of a characteristic of the product that may cause damage and the danger of such characteristic (or alternatively, Defendants would have acquired such knowledge if they had acted as a reasonably prudent manufacturer), and thus are liable for damages suffered by Plaintiff, which arose as a consequence of Defendants' failure to use reasonable care to provide an adequate warning of such characteristic and its danger to users when such knowledge was acquired.

COUNT III – NEGLIGENCE & GROSS NEGLIGENCE

46. Plaintiff hereby restates and alleges each and every allegation set forth above with the same force and effect as if herein repeated and set forth.

47. Defendants are the designer, manufacturer, seller, and/or supplier of the device implanted in Plaintiff.

48. When placed in the stream of commerce, Defendants' CR-Flex (GSF) was not accompanied by any meaningful warnings regarding the risk associated with it. The warnings given by Defendants were silent as to the particular risks for which the device has been recalled and/or suspended.

49. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of its implant.

50. Defendants were negligent in the design, manufacture, testing, advertising, marketing, promotion, and labeling of the product, as well as in their failure to warn, and failure to properly instruct and/or train physicians in the use of its implants, including the implant received by Plaintiff. Defendants knew or should have known that patients, such as Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

51. The CR-Flex (GSF) was unreasonably dangerous and defective because:

a) The manufacturing processes for the prosthesis and certain of its components did not satisfy the Food and Drug Administration's standards for the devices;

b) The failure of the manufacturing processes for the implants and certain of its components to satisfy the Food and Drug Administration's standards for the implants resulted in unreasonably dangerous manufacturing defects;

c) The Defendants failed to warn of the unreasonable risks which were created by these manufacturing defects; and/or

d) The Defendants failed to properly instruct and/or train implanting physicians, thereby creating an unreasonably dangerous and defective device.

52. Defendants' actions as described herein constitute knowing omissions, suppression or concealment of material facts made with the intent that others would rely upon such concealment, suppression or omissions in connection with the marketing of the devices.

53. The behavior of the Defendants demonstrates that they acted unlawfully and

negligently, used or employed unconscionable commercial business practices, engaged in deception, fraud, false pretenses, false promises or misrepresentations, and/or perpetrated the knowing concealment, suppression or omission of material facts with the intent that consumers, including Plaintiff, would rely upon such concealment, suppression, or omission, in connection with the sale or advertisement of its implants.

54. Defendants had actual knowledge that the product was defective, and further, that there was a substantial likelihood that the defect would cause the injuries which are the basis of this lawsuit. Defendants willfully disregarded that knowledge in the manufacture and distribution of the product.

55. Defendants' conduct in designing, manufacturing, and distributing the product, despite actual knowledge of its defective condition and propensity to dislocate once implanted constitutes gross negligence, as it is "conduct so reckless as to demonstrate a substantial lack of concern for whether injury results". MCL 600.2945(d)

56. As a direct and proximate cause and legal result of the Defendants' failure to provide appropriate warnings, instructions and/or training for Plaintiff's implant, and as a direct and legal result of the negligence, other wrongdoing and actions or omissions of Defendants described herein, the devices were implanted into Plaintiff and Plaintiff has suffered damages as described previously.

57. Defendants' negligence and gross negligence were the direct and proximate cause of Plaintiff's injuries and damages as set forth herein.

COUNT IV - MISREPRESENTATION

58. Plaintiff hereby restates and alleges each and every allegation set forth above with

the same force and effect as if set forth herein and repeated at length.

59. Defendants made misrepresentations and/or omissions of material facts, including, but not limited to:

a) That Plaintiff's implant was fit for its intended use;

b) That Plaintiff's implant was of merchantable quality;

c) That Plaintiff's implant was safe and efficacious in the treatment of Plaintiff's medical condition;

d) That Plaintiff's implant would function as intended when necessary;

e) That Plaintiff's implant was defective, such that it would fail to function as intended; and

f) That Plaintiff's implant was inherently dangerous.

60. These representations and/or omissions were false and misleading at the time they were made.

61. Defendants negligently and carelessly made the foregoing misrepresentations without a basis.

62. Defendants were aware that they did not possess information on which to accurately base the foregoing representations and concealed from Plaintiff that there was not reasonable basis for making said representations herein.

63. When Defendants made the foregoing representations, they knew or should have known them to be false.

64. In reliance upon the foregoing misrepresentations by the Defendants, Plaintiff was induced to and did subject herself to the use of the CR-Flex (GSF). If Plaintiff had known of the

true facts, she would not have taken such action and risk. Plaintiff's reliance on Defendants' misrepresentations and omissions was reasonable because said representations were made by individuals and entities in a position to know the true facts.

65. As a result of the foregoing misrepresentations by Defendants, Plaintiff will continue to suffer injury, expense and economic loss as previously described.

COUNT V -
BREACH OF WARRANTY OF QUALITY AND FITNESS

66. Plaintiff restates each and every allegation set forth above with the same force and effects as if set forth herein and repeated at length.

67. Defendants are in the business of designing, manufacturing, and/or supplying and/or placing into the stream of commerce the CR-Flex (GSF) for consumers.

68. By placing the CR-Flex (GSF) into the stream of commerce, Defendants impliedly warranted that it was merchantable, fit, and safe for its intended use.

69. The CR-Flex (GSF) placed into the stream of commerce by Defendants was defective and accordingly, was neither fit, safe, nor merchantable for its intended use.

70. The defects in the CR-Flex (GSF) designed, manufactured and/or supplied and/or placed into the stream of commerce by Defendants were present at the time the product left Defendants' control.

71. Defendants breached its warranties of quality and fitness for the CR-Flex (GSF) because said product was defective, unmerchantable, and not fit for its intended purpose.

72. Plaintiff was a foreseeable user of the CR-Flex (GSF) designed, manufactured and/or supplied and placed into the stream of commerce by Defendants.

73. As a direct and proximate result of Defendants' breach of warranties of quality

and fitness, plaintiff will continue to suffer injury, expense, and economic loss as previously described, rendering Defendants liable for said damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief from this Court as follows:

a) That process issue according to law;

b) That Defendants be duly served and cited to appear and answer herein, and that after due proceedings are had, that there be judgment in favor of Plaintiff and against Defendants for the damages set forth above, along with court costs, pre-judgment and post-judgment interest; and,

c) For all such other relief as to which Plaintiff may show herself entitled to, including without limitation:

a) pain and suffering (past and future);

b) wage loss (past and future);

c) earning impairment;

d) medical expense (past and future);

e) loss of enjoyment of life;

f) mental anguish and distress;

g) permanent injuries and impairment; and

h) attorney fees.

Respectfully Submitted,

Dated: May 17, 2012

/s/ Jules B. Olsman

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JURY DEMAND

NOW COMES the plaintiff, DANIELLE GARDNER, by and through her attorneys, OLSMAN, MUELLER, WALLACE & MacKENZIE, P.C., and hereby demands a trial by jury of the above-entitled cause.

Respectfully Submitted,

/s/ Jules B. Olsman

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